

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Group Art Unit: 1595

WARREN WARD

Examiner: Tigabu Kassa

Serial No.: 10/595,033

Filed: January 4, 2006

For: **COMPOSITIONS COMPRISING COMPONENTS COATED
WITH A LIQUID IMPERMEABLE BUT GAS PERMEABLE
LAYER, USE THEREOF FOR TREATING CUTANEOUS AND
OTHER EXOCRINE GLAND DISEASES**

Attorney Docket No.: WAW0101PUSA

**DECLARATION OF WARREN WARD
UNDER 37 C.F.R. § 1.132**

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

I, Warren Ward, do hereby declare and state as follows:

1. I graduated from UK Grammar School with certificates in English, French, English Literature, Pure Maths, Applied Maths, Physics, Chemistry, Art, and Advanced Level Pure Maths and Applied Maths.

2. My professional background is one of executive or general manager, with employment associated with the management of large holiday centres in the UK from 1964 to 1979. From 1979 to 1996, I held a Chief Officer appointment in UK Local Government. From 1996 to 2000, I lectured in information technology at Llandrillo College, UK. I was also a Fellow of the Institute of Trade Valuers UK, and pursued that profession until 2002. From 1984 onwards, I undertook part time investigation into the health status of UK citizens and the etiology of chronic conditions. By 2002 this became a full time occupation.

3. I am the sole inventor of the claimed subject matter of U.S.

Application Serial No. 10/595,033, hereinafter the "Application" and am familiar with the content of the Application and the Office Action dated January 7, 2009 received from the United States Patent and Trademark Office, hereinafter the "Office Action."

4. I understand the pending claims 7-11 and 24-33 are rejected under 35 U.S.C. § 101 as lacking patentable utility (Office Action, page 3). In particular, the Examiner opines that "there is insufficient evidence to show that a compound which is not released on or into the body can have any medically beneficial effect." *Id.*

5. The pending claims in current form are directed to a preparation that can be used as a medical device. The claimed preparation is not a conventional pharmaceutical composition or compound that must generally be dissolved into body circulation for cellular uptake and subsequent metabolism. Please see relevant portions of the Amendment submitted concurrently herewith.

6. The claimed preparation is at least partly based on the understanding that all living cells sense and respond to their environment by means of mechanisms known as cell signaling pathways. These mechanisms are part of a complex system of communications that govern basic cellular activities and coordinate the actions of cells.

7. Cell signaling refers to the process by which extracellular substances produce an intracellular response. This is an essential and widespread biological phenomenon by which hormones, neurotransmitters, and other agents regulate cellular function. In some cases, the natural agent inducing the response is present on the surface of a nearby cell, or is present in the extracellular matrix on which cells reside.

8. From 2001 onwards, I set out to experiment and investigate the creation of an exogenous signaling pathway as a therapeutic method of cell signaling via epithelial surfaces and thus activating total body cellular signaling. This therapeutic method is particularly useful for chronic conditions where the physiology has moved away from

normal natural interactive controls or homeostasis, e.g. essential hypertension. There are five great advantages of this method of treatment:

- Molecules can be used to affect cell signaling without the molecules having to be dissolved in body fluids.
- Molecules can be used to reinstate normal homeostasis of humans and animals with chronic conditions, in contrast to conventional drugs which often interfere with normal physiological processes.
- Molecules which are found naturally in the body can be used to beneficially affect cell signaling pathways.
- Since, in contrast to conventional drugs, there is no dissolution or elimination, the molecules can be carefully targeted to avoid all side effects, creating a high level of safety.
- Molecules, including established therapeutic molecules, can be used to affect cell signaling pathways more effectively, but much more safely than conventional drugs.

9. I reasoned that the creation of an exogenous signaling pathway would require both the presence of introduced molecules in proximity to the epithelial surfaces, and transient presentation of such chemicals in microscopic quantities, or apparent microscopic quantities, to the cells of the epithelial surfaces. Induced changes in their immediate environment could be calculated to elicit a response by the epithelial cells.

10. After a large number of experiments, it was found that a rapid response could be achieved by transient presentation of appropriate chemicals to the epithelial surface. A working method was determined to enclose chemicals within a microscopically perforated robust coating together with arrangements to ensure that these coated chemicals had constant movement, or apparent constant movement. A number of coated products can be formulated in this way.

11. My research and elucidation of the 'Smart Cell Signal'™ led to the development and manufacture of the unique Equiwinner™ patches designed particularly for horses.

12. Following the principles for fuzzy logic transient presentation of sealed therapeutic chemicals to the epidermal surface, the Equiwinner™ patches have two signal

nodes containing a balance of sealed electrolytes, such as sodium chloride, are mounted on each patch. The electrolytes are coated in such a way as to provide for microscopic apertures facing the epidermis.

13. Equiwinner™ patches were originally designed to activate angiogenesis of skin capillaries so as to reduce the excessively high blood pressure of racehorses under maximum exertion. This high pressure was known to cause exercise induced pulmonary haemorrhage (EIPH), or horse bleeding. This is a very common problem in horses. Equiwinner™ also corrects anhidrosis, or non-sweating, another previously untreatable condition in horses, particularly those in hot climates. The 'Smart Cell Signal™ is also effective throughout the body in restoring full hydration of horse body tissues, indicating persistence of the induced cell to cell signaling. Another condition for which Equiwinner™ is rapidly effective is equine rhabdomyolysis, or azoturia, commonly known as "tying-up".

14. I, the discoverer of the 'Smart Cell Signal™, believe that I have described for the first time in history the full aetiology of the previously unknown cause of automatic head shaking in horses, which can be corrected using Equiwinner™.

15. Further information related to the Equiwinner™ patches may be found at www.equiwinner.com, www.signal-health.com, and www.equinereset.co.nz.

16. The "EQUIWINNER" dermal patch for horses included a metalized foil label 100mm by 160mm, one side of which was coated with an adhesive suitable to allow the patch to cling firmly to the skin hairs of a horse. On this adhesive side of the patch were two plastic cup discs, each of 10mm diameter, fixed centrally on the patch at a distance of 60mm apart. The cup discs were filled with sodium chloride sealed within a matrix of white beeswax, the wax being hardened with talc and cornstarch.

17. The "EQUIWINNER" patches have been sold to professional horse trainers in various countries including the United States, United Kingdom, Australia and New

Zealand. The retail selling price has been between 123 and 130 US dollars (or the equivalent) plus carriage and tax where applicable, for a box of ten patches, plus two spare patches.

18. The "Equiwinner" patches according to the claimed invention have been very well received by the trainers, representing the only effective treatment known for the market. The total numbers of the "Equiwinner" patches sold in the last four consecutive calendar years were 5,000 patches, 11,000 patches, 18,000 patches, and 24,000 patches, with a market value of several hundred thousand dollars for year 2009. The magnitude of increase in sales is further reflective the high quality of the "Equiwinner" patches according to the claim invention. This secondary consideration strongly supports both utility and patentability of the claim invention.

19. Based on the above, I respectfully submit that the utility of the claimed invention has been abundantly established at least through its worldwide commercialization and successes associated therewith.

20. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application and any patent issued therein.

Signed: Warren Ward
Date: APRIL 3, 2009

Warren Ward